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PRESCRIPTION DRUG PRICING: HOW MUCH IS TOO MUCH?

I.

INTRODUCTION

Few items are so central to Americans as prescription drugs. In a time of increasing life spans, Americans use ever more prescription drugs and these trends will likely continue. However, Americans know little about the process of drug development itself. Only a limited number of people understand the regulatory approvals through which each new drug must travel. Fewer still understand the scientific underpinnings of a drug. Many of the changes in laws that affect prescription drugs can have substantial impact on Americans, across age, class and racial divides. Yet most citizens follow few of these changes. There is one exception to this relative distance between drug laws and the public: prescription drug prices. Americans understand the prices they pay for drugs, from breakthrough new treatments for cancer and AIDS to time-tested antibiotics that nearly all Americans will take at least once in their lives. Many people may have the sense that the prices that they pay are too high. These reactions may be visceral rather than empirical. Nevertheless, there is the sense that Americans are paying more for drugs than their counterparts in other industrialized nations.

Politicians are not unresponsive to these sentiments. In a sense, political leaders give shape and add substance to millions of anecdotes related by their constituents around the country. Leaders in Washington and state capitols have attempted to address these issues by advancing a variety of policy prescriptions. The issue of prescription drug prices is widely known generally. However, proposals to address it are complex and the ramifications range from elegant simplicity to potential catastrophe. Undoubtedly, those constituents, whose

pressure Washington can be very responsive to, are likely to be as divided on these issues as the scholars and legislators.

The relative significance of this issue in the public domain has varied. It is worth noting that the issue is not a new one. Senator Estes Kefauver conducted a study on drug prices in the 1950s out of concern that his constituents were paying excessively for prescription drugs. The issue surfaced during the debates over the creation of Medicare in the 1960s. Although the issue lay relatively dormant for a time, the election of 1992 brought this matter into clearer focus than it had been in some time. Typically, the issue is paired with overall proposals for reforming the health care delivery system, and 1992 was no exception. The Clinton Administration's health care plan ("Clinton Healthcare Plan") not only included a number of provisions related to pharmaceuticals, but was accompanied by a series of scathing remarks by the President and members of his Administration directed at drug makers. A temporary drop in the price of the publicly traded securities of the pharmaceutical companies was one consequence of the President's proposal. The issue subsided after the President's proposals were shelved and his party was subsequently swept from Congress. However, the issue has returned in the last two years, although in a slightly different vein. There has been a great deal of debate about adding a prescription drug benefit to the Medicare program, which provides health insurance to the elderly. As it stands, Medicare only pays for drugs administered in hospitals. Many observers view the lack of such a benefit as the single major gap in the Medicare program. The Administration's public comments about the pharmaceutical industry have become less caustic and their policy initiatives more moderate. Approaches aside, the issue of prescription drug prices and potential ways to address the issue have returned to the public forum. Even though the current debate may be about Medicare, price controls and their ramifications lurk beneath the surface.

The easiest way to frame the debate is between those forces advocating a complete laissez-faire approach to drug pricing, pitted against individuals who desire strict federal price controls. At some times and places,

the debate is that starkly presented; in other cases, it is not. There are numerous proposals for controlling the increasing cost of prescription drugs. Some of these rely on more market-based approaches; some of them resemble traditional command and control. Many of the arguments that the free market school makes apply to all policies to control drug prices. At other times, their critique is aimed only at those policies that are the most heavy-handed. This analysis will explore the general policy of price controls on prescription drugs, which may or may not be a part of a future Medicare prescription drug benefit. In all cases, the debate is both fascinating and combustible.

II.

DRUG PRICES: AMERICA AND ABROAD

The first way in which advocates of government control of drug prices typically approach the problem is to look at the prices themselves. The first questions that need to be asked are: Are drug prices too high? How do we determine what is a high price? Not surprisingly, there is little agreement. Not only do some people view prices as too high and some just right, there is no consensus on how to measure prices. To get a general understanding, one has to look at studies to see where drug prices stand. Some examples of drug prices focus solely on costs measured in absolute terms, many of which seem exorbitant. A new drug Ceredase for treating the rare Gaucher's disease was priced at \$100,000 per year. A new plasmogen activator for heart attack victims was priced at \$2,800 per dose.¹ These prices, standing alone, are understandably irksome to many people, but absolute numbers mean little in the absence of a relevant benchmark for comparison or an understanding of industry cost structures and profit levels.

¹Alan Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 296 (1994).

Absolute prices notwithstanding, drug price studies are typically structured in one of two major ways: examinations of annual increases in prices of drugs already on the market and cross-national comparisons. These methods are more constructive than looking at absolute prices. Drug prices have generally increased at a greater level than the real inflation rate, ordinarily measured by the Consumer Price Index (“CPI”). An earlier General Accounting Office study (“GAO”) found that median price increases between 1985 and 1991 of a basket of 29 drugs increased 124.8% while the CPI increased only 26.2%.² The overall CPI for prescription drugs increased at an average rate of 10.6% between 1985 and 1991, double the 5.5% increase for all goods.³ The 1992 GAO report also showed that during the 1980s, average drug price increases were triple the inflation rate.⁴ The general inflation rate from 1980 to 1990 was 58%; the rate for drugs was 152%.⁵ In some years, the prices have galloped ahead of the index, while in other years the increases have been more negligible. It might seem as though using the prices themselves as an argument in favor of control is like gathering data without synthesizing it. However, many of these advocates for consumers, the elderly or the uninsured believe that the prices themselves are the greatest argument for government intervention.

A study by Families USA examined the price increases of a variety of drugs commonly used by seniors during calendar year 1998. This study has been widely cited by congressional critics of the drug makers. The study determined that the fifty drugs most frequently used by seniors increased at more than twice the rate of inflation.⁶ One-third of the drug prices rose more than four times the rate of inflation. Perhaps the most

²Baruch Brody. *Ethical Issues in Drug Testing, Approval, and Pricing: The Clot-Dissolving Drugs*. (New York: Oxford Press, 1995), p. 231.

³Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN J.L. & PUB. POL’Y 89, 90 (1993).

⁴Daniel Greenberg, “*Gallop drug prices evoke a political reaction*”, LANCET, Sept., 5, 1992, Vol. 340 Issue 8819, p. 597.

⁵Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN J.L. & PUB. POL’Y at 90.

⁶Families USA, *Drug Companies Put the Squeeze on Older Americans* (visited February 14, 2000) <<http://www.familiesUSA.org/drugrel.htm>>

egregious single example was the drug Lorazepam, used in the treatment of Parkinson's Disease and some convulsive illnesses. The price of the drug increased 179 times the inflation rate during the period of the study. The same study found that the median net profit of the manufacturers of those drugs was more than four times larger than other Fortune 500 companies.⁷

President Clinton, who has periodically advocated greater government regulation of the pharmaceutical industry, often tells anecdotes about elderly residents in border states who are forced to travel to Canada to obtain affordable prescription medicines. This presages a second way that drug prices are often shown to be excessive, namely, through cross-national comparisons. These studies often compare American prices to European or Canadian prices. A GAO study indicated that Americans pay 32% more for a basket of 121 drugs than do Canadians.⁸ A Public Citizen study of prices of antidepressants found that Americans pay between 1.7 and 2.9 times more for these drugs than Europeans.⁹ The Minority Staff Reports, discussed later in a different context, showed similarly large differentials between U.S. prices and those of Canada and Mexico. Based on these studies, and others modeled after them, the landscape of drug prices as explained by consumer advocates is simple: Americans pay much more than citizens of other nations, and prices rise substantially faster than inflation.

There is neither a consensus on what is a "fair" price for a drug, nor agreement on how even to make that determination. First, some argue that while list prices for drugs seem high in certain studies, there are better ways of conducting cross-national price comparisons. One alternative is "purchasing power parity". That is, one can look to the percentage of disposable income spent on prescription drugs to gauge the burden that such purchases place on a typical consumer. When this measure is used, Americans appear to spend less on

⁷Ibid.

⁸Baruch Brody. *Ethical Issues in Drug Testing, Approval, and Pricing*, p. 232

⁹Larry Sasich and Fuller Torrey, *International Comparison of Prices for Antidepressant and Antipsychotic Drugs* (visited February 26, 2000) <<http://www.citizen.org/hrg/publications/1446.htm>>

prescription drugs than many other industrialized nations.¹⁰ In 1991, the average American worker worked 14.2 hours to pay for a year's supply of drugs, as compared with 19.8 hours for Germans and 20.4 hours for the French.¹¹ Some assert that this is because Americans use fewer drugs in response to the higher list prices. That may be, but it also may be that the cheaper European prices mean that those citizens are using more drugs, often unnecessarily, simply because they are cheaper. Another frequently cited problem with price indexes is that they do not account for improvements in drug quality. This is an important critique. In the context of the CPI, it has often been noted that the change in prices of technology products, such as computers, do not sufficiently take into account the fact that each generation of computer is far superior to its predecessors. Hence, any analysis of cost that fails to account for these quality improvements will show artificially high prices. There is no reason why this logic should not apply to prescription medicines as well. A recent study which purported to expose price gouging in new antidepressant medicines seemed to concede as much in saying, "Recently introduced anti-psychotic and anti-depressant drugs may have advantages over older drugs but their high cost may be a major limitation to their availability."¹² Without accounting for the marked improvements in these and other new drugs over their predecessors, the prices are likely to appear exorbitant. This remains an essential critique of studies purporting to show prices galloping ahead of the CPI. These price indexes also typically analyze brand name drugs without taking into consideration possibilities for generic or even over-the-counter ("OTC") substitution. U.S. prices for generic drugs and OTCs are relatively cheap in international terms, and their inclusion would deflate the overall price differentials.

Another industry response is that while drug prices may have been high at some point, they have begun to go down. The prices of prescription drugs skyrocketed throughout the 1980s, giving President Clinton

¹⁰Robert Goldberg, *Policy Report No. 230* (visited February 14, 2000) <<http://www.ncpa.org/studies/s230/s230.html>>

¹¹Donald Drake and Marian Uhlman. *Making Medicine, Making Money*. (Kansas City, McMeel Press, 1993), p. 96.

¹²Larry Sasich and Fuller Torrey, *International Comparison of Prices for Antidepressant and Antipsychotic Drugs* (visited February 26, 2000) <<http://www.citizen.org/hrg/publications/1446.htm>>

ammunition in his crusade to reform the health care system when he assumed the Presidency. Toward the late 1990s, however, the trend has slowed markedly, with increases of roughly three to four percent annually.¹³ The pharmaceutical industry trade association is eager to point these facts out as well. Specifically, they say that increasing market competition resulted in only a 2.1% increase in calendar year 1996—the smallest in twenty years.¹⁴ Another study found that drug prices increased by 3.4% in the third quarter of 1998.¹⁵ Prices for the top ten selling prescription drugs increased 3.2% over the same period.¹⁶ Even before President Clinton was elected, price increases were slowing from the torrid pace of the 1980s. It is worth making a few observations at this point. First, there is no question that drug price increases have moderated in some periods of the middle and late 1990s and part of this is related to the efforts of managed care to drive down health care spending overall. However, some of this may have to do with the political pressure and threats of government controls emanating from the Clinton Administration. The second point is more pronounced. Although price increases have been reduced, they still are running well above the rate of inflation. An annual price increase of 4%, for instance, would be twice the rate of inflation during some quarters of the late 1990s. Although inflation has been running low, and price increases by drug makers have diminished somewhat, the increases typically remain well above inflation in percentage terms.

One of the most recent and comprehensive set of studies which attempted to measure drug prices was the Minority Staff Reports (“Staff Reports”) which were analyses commissioned by a number of Democratic members of Congress. The Staff Reports examined drug prices in dozens of congressional districts around the country. For the purposes of this paper, the results of a report prepared for Rep. Thomas Barrett of

¹³Health Insurance Association of America, *Prescription Drugs: Cost and Coverage Trends* (visited February 25, 2000) <<http://www.hiaa.org/news/news-state/prescriptiondrugs.htm>>

¹⁴Pharmaceutical Manufacturers Association, *The Market is Working* (visited February 14, 2000) <<http://www.pharma.org/issues/market/html>>

¹⁵IMS Health, *IMS Health Reports U.S. Prescription Drug Prices Annual Rate of Change Holds at 3.4 Percent* (visited February 25, 2000) <http://www.imshealth.com/html/news_arc/11_13_1998_126.htm>

¹⁶Ibid.

Wisconsin can be used, since methodologically each report was identical. These studies demonstrated gross price differentials between prices charged certain federal agencies in the Federal Supply Schedule (“FSS”) and private consumers (in this case, in Barrett’s district). The FSS is in many ways a proxy for the prices charged to larger purchasers of drugs. In any event, it is used here to show that individual consumers are not receiving the lowest prices charged. Other aspects of the report also used cross-national comparisons and again found great disparities, especially when U.S. prices were compared with Canada and Mexico. In Barrett’s district, an 86% price differential was found between prices charged to the FSS and to individual consumers. The most egregious single difference was for the drug Zocor to treat cholesterol, where a 147% disparity was found.¹⁷ This report demonstrates the first major fault line in this debate. The advocates of government intervention use a study that shows high prices as their main argument for price controls. The opposition proceeds to attack it with a series of critiques in terms of method and approach. Many of the criticisms offered by opponents of price regulation are strong, but it is not always clear that their alternative approaches to price measurement do not suffer shortcomings of their own.

Analyses of the Staff Reports is useful not only because they are new, but also in order to view the sort of arguments often made against many of these studies. First, the Staff Reports randomly chose a few of the most popular drugs to survey. Most of these drugs are mature and have a large number of competitors. These are the very sort of drugs where large discounts are likely to be offered to the federal government to get on the FSS. Hence, the disparities may be biased here because the drugs with the largest federal discounts were chosen, creating artificially high gaps between consumer prices and FSS prices.¹⁸ Many other price studies suffer the same shortcomings. The second principal criticism is that the Staff Reports, like many other price studies, does not account for generic substitutes, which are often more available in the U.S. and

¹⁷Minority Staff Reports, *Prescription Drug Pricing in the Fifth Congressional District in Wisconsin: Drug Companies Profit at the Expense of Older Americans* (visited March 1, 2000) <http://www.house.gov/barrett/drug_company_profits.html>

¹⁸Patricia Danzon. *Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies*. (Washington, DC: AEI Press, 1999), p. 6-7

can cut costs considerably. Finally, it is asserted that the FSS price is essentially a wholesale price whereas the prices paid by consumers is a retail price, making the comparison structurally inaccurate.¹⁹ However, in choosing the most widely used drugs at least, the Congressional Democrats purported to be surveying the drugs whose prices have the greatest effect on the greatest number of people. From this standpoint, choosing the most popular drugs did not distort the study, but made it even more persuasive. A price comparison of all drugs, by contrast, while technically more inclusive, might bear little relation to the predicament faced by most consumers.

In addition to the alleged problems with the FSS/consumer aspect of the Staff Reports, Danzon makes especially strong criticisms of the cross-national studies included in the Staff Reports. According to her, the Canadian comparisons are flawed for a number of reasons. First, Canada has a price control regime, which means that the Staff Reports are not comparing two *markets*, but rather, one market and one command regime. Her primary critique is that the Staff Reports use a sample of only ten highly priced drugs, weighted equally without regard to market share. Also, the unit of measurement, instead of being a “per dose” or “per gram” measurement, was based on a pack of 100 tablets, which are unavailable in Canada. Hence, the 100 tablet basket was provided for by dividing a 1000-tablet pack by ten, which artificially deflates the Canadian prices.²⁰ When Danzon constructed her own index based on price per gram of a drug, where a different basket of drugs was weighted by market share, she found only a 13% difference in price between the U.S. and Canada, far smaller than that shown by the Staff Reports.²¹ As a general matter, Danzon is right that only a comparison based on a gram is accurate since a dose or a pack in the U.S. may be stronger than a dose or a pack elsewhere, thus making dose/pack comparisons potentially inaccurate. She also argues

¹⁹Ibid., p. 7-9.

²⁰Ibid., p. 29.

²¹Ibid. p. 31-32.

that comparison with Mexico is likely to be inappropriate under any circumstances. A much poorer, less developed nation, Mexico can be expected to have lower prices for most goods. Further, Mexico did not grant patent protection to drugs until 1991, and even now, many drugs are available on an over-the-counter basis.²² The U.S. and Mexico are simply too different for reliable comparisons. The criticisms of the Staff Reports and other drug price studies show that outcomes can depend heavily on which drugs are chosen. Just as Danzon criticized the Democrats who designed the Staff Reports for selecting one basket of drugs, an impartial observer might ask why Danzon's selection of drugs is likely to be any more accurate. There is ample room for manipulating the drugs and quantities chosen in order to get a different set of results. Another issue with regard to drug prices themselves is that the U.S. may actually be subsidizing the rest of the world because they have price controls and we do not. Essentially, the pharmaceutical industry is like other formerly regulated industries, such as telecommunications and railroads, in the sense that it is viewed as an essential foundation for other parts of the free market to operate. However, it is unlike these other industries in that it is much more of a worldwide business. Pharmaceutical firms view profits from a global perspective. Thus, a sale at a tightly regulated price in France may be made even though there is a limited profit. The narrow profit may be accounted for by charging higher prices in non-price regulated markets. These unregulated markets, principally the U.S., may allow the drug makers to recoup the high costs of R&D.²³ This argument is supported by a number of observers on both sides of the debate, although economists are likely to be skeptical of it. Presumably, drug companies were already charging the profit-maximizing price in each market, as traditional economic theory would dictate. Any increase in the U.S. price would theoretically cause a drop in U.S. sales that would seem to offset any benefits from the increase in cost. The extent to which drug companies attempt to use the U.S. to recoup the costs of selling elsewhere is hard to gauge, but the idea does have its supporters. The idea of making Americans bear the burden of

²²Ibid. p. 32-34.

²³John Wechkin, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection*, 5 PAC. RIM L. & POL'Y J. 237, 250 (1995).

foreign regulatory systems does underline the idea that pharmaceuticals is a global business and that policy decisions can have a global impact.

The arguments about drug prices sometime seem to exist in a vacuum. Drugs are but one tool in the medical arsenal to treat any variety of conditions. Therefore, drug prices should be viewed in the overall context of health care spending. Drug companies argue that while their prices may seem high by themselves, when one considers the expensive alternatives like surgery, drugs are a bargain. Many studies have demonstrated that drug treatments are vastly cheaper than many medical alternatives. For instance, a drug treatment that obviates the need for extended hospital stays or complicated surgeries may save vast sums of money. Some have argued that Medicare coverage of prescription drugs would actually *reduce* health care spending, because drugs could substitute for the more expensive treatment alternatives that are presently covered. It has been stated that every dollar spent on prescription drugs resulted in a four dollar decline in spending on hospitals.²⁴ For instance, the National Bureau of Economic Research found that in the period of 1991-1995, the cost of treating acute depressive conditions dropped by one-quarter due to the introduction of new medicines. Similar studies with HIV show that although new generation protease inhibitors are extremely costly, their prices are more than offset in reduced hospitalization costs. The pharmaceutical industry also claims that new ulcer drugs have dramatically cut the number of ulcer surgeries, which cost over \$7,000.²⁵ The contraceptive device Norplant, which was heavily criticized for its \$365 price, in fact translated to a cost of only twenty cents a day over its five year life, somewhat less than the cost of oral contraceptives.²⁶ Whether one looks at AIDS, cancer, heart disease or any number of other conditions, there is support for the fact that treatments with prescription drugs can offset health care costs incurred by alternative

²⁴Robert Goldberg, *Policy Report No. 230* (visited February 14, 2000) <<http://www.ncpa.org/studies/s230/s230.html>>

²⁵Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN. J.L. & PUB. POL'Y at 91.

²⁶Robin Margolis, *Prescription Drug Pricing: Do Competitive Forces Operate in the Pharmaceutical Marketplace?*, 11 NO. 2 HealthSpan 9, 10 (1994).

treatments. When price controls are implemented, especially through the mechanism of universal health insurance, governments typically cap total spending, and assign a particular percentage of overall spending to pharmaceuticals. This is known as component or global budgeting. This may not recognize the interchangeable nature of some drugs and some surgeries or hospital visits. Hence, allowing greater spending on drugs might cut spending in other areas, but such “global budgets” do not permit this dynamic process to occur. Another way to look at this is to note that spending on prescription drugs accounts for only seven percent of total health care costs.²⁷ So trying to force these expenditures down without looking at the total health care spending picture might have little effect on overall health care costs. European countries and the Clinton Healthcare Plan all adopted some form of component budgeting. However, not only do such programs make drug costs look high by failing to account for the expensive surgeries and hospital stays for which they are substitutes, such strategies may actually *increase* overall health costs. The reason for this is that if a drug budget is capped and a particular treatment is disallowed, but the surgery/hospital budget has a higher cap, the patient may be directed to the more costly surgery over the drug. Over time and over a variety of therapeutic categories, such substitution is both foolish and costly from a budgetary standpoint. This argument proves that while some believe that drug prices are ridiculously high, others say they are the bargain of the day.

Not everyone agrees on what elements go into the pricing of new drugs or the increases in the prices of existing drugs. Corporate “greed” may or may not be a factor, but to say that it is the only influence is plainly wrong. The industry usually points out, in addition to the costs of R&D, other explanations for high costs. Some argue that the American drug approval system involves more rigorous testing for safety and effectiveness

²⁷Michael Weber, *Impact on the Pharmaceutical Industry of Changes in the American Health Care System: A Physician's Perspective*, 24 SETON HALL L. REV. 1290, 1322 (1994).

than many European systems. While this may ultimately protect consumers, in the interregnum, it increases the costs of getting new drugs to market. Another factor is the tort system. Britain, for instance, has a “loser pays” provision in many civil cases. This serves as a substantial impediment to the filing of tort actions. Many continental European countries greatly restrict or altogether bar class actions. All of this leads to a more enterprising environment for litigation in the U.S., which tends to increase costs, part of which is likely to be passed on to consumers in the form of higher prices. The simplest answer to the etiology of drug prices, however, is that American prices are higher to a substantial degree because the government here does not force them down.

The trajectory of the debate so far is clear: the consumer advocates have studies showing excessive drug prices and the industry’s allies maintain that these studies are misleading either in methodology or in their conclusions. Once the consumer advocates and others establish the fact of high prices, they attempt to show the negative effects of these prices. Americans may well pay more for bicycles or candy than the French or the Swedes. Few people would talk about those issues and certainly it would be difficult to find a study exploring that topic. Drugs are viewed as not simply essential, but as peculiarly closing society’s most vulnerable out of the system. The reason why this issue is so potent is because the U.S., unlike most other nations, does not have a universal health care plan. The U.S. has a Medicare program, which provides health insurance to seniors and a Medicaid program that targets the poor. In the absence, however, of universal coverage, high prices will have the effect of putting drugs out of the reach of many Americans and the debate will continue. The Staff Reports stated that high drug prices particularly burden seniors, since they spend three times more on health care than those under age 65. Those over 65 take one-third of all prescription drugs.²⁸ No one doubts that being unable to afford needed drugs is devastating. There is, though, great disagreement

²⁸Minority Staff Reports, *Prescription Drug Pricing in the Fifth Congressional District in Wisconsin: Drug Companies Profit at the Expense of Older Americans* (visited March 1, 2000) <http://www.house.gov/barrett/drug_company_profits.html>

about how to measure drug prices and whether they are too high, and this first part of the debate is unlikely to be settled soon.

III.

THE PHARMACEUTICAL INDUSTRY: STRUCTURE AND INCENTIVES FOR RESEARCH

Once proponents of additional government regulation make their initial case that drug prices are exorbitant, the opposition response typically focuses on the structural nature of the pharmaceutical industry. The first industry response is both the most frequently recited as well as the strongest: the high cost of research & development (“R&D”) of new drugs. The cost of developing a new drug was estimated to be \$54 million in 1976, \$231 million in 1987 and \$350 million by the early 1990s.²⁹ It usually takes about 11-12 years to begin to reverse the negative cash flow effects of developing a new drug.³⁰ Only five of every four thousand laboratory compounds ever merits human testing. Of these five, only one ever becomes a drug for sale.³¹ Between 1970 and 1979 only 30% of new drugs recouped their R&D costs.³² Further, about 17% of profits are reinvested in R&D, thus making future discoveries heavily dependent on present profits.³³ Not only are the costs high, but the few successful drugs must make up for the costs of testing all of the failures. These expenses are present throughout the drug development process, in pre-clinical as well as clinical phases and later in marketing the drugs to the public. Because of the great time lag between the beginning of research

²⁹Michael Weber, *Impact on the Pharmaceutical Industry of Changes in the American Health Care System*, 24 SETON HALL L. REV. at 1300.

³⁰Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Chapter 3, ¶ 10 (visited February 29, 2000) <<http://www.cbo.gov>>

³¹Alan Fisch, *Compulsory Licensing of Pharmaceutical Patents*, 34 JURIMETRICS J. at 302-303.

³²Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN. J.L. & PUB. POL’Y at 91.

³³*Ibid.*

and commercial payoffs, there is also a large opportunity cost of capital. Money invested in long-term R&D might be spent on other investments in the meantime. The 1997 FDA Modernization Act contained a number of provisions designed to expedite the approval process. The reality of years in testing and approval remains even with the changes. The pharmaceutical business seems somewhat different from others. More than other industries, benefits are far off from initial research, the odds are against success and the costs are incredibly high. Nobody argues that developing drugs is cheap or risk free. The figures cited regarding R&D costs for a new drug often include the opportunity cost of capital, and some say this inclusion inflates the actual cost of R&D for a new drug.³⁴ Yet the general principle of high costs and risky research is accepted even by some of the industry's critics.

The Clinton Healthcare Plan would have imposed a form of price controls on the pharmaceutical industry. Opponents of price regulation believe that this plan would have resulted in a decidedly negative impact on R&D and the ultimate development of new drugs. Since the Clinton Plan was the most recent attempt to control prices, an examination of it gives one a good sense of the R&D issue. The Clinton Plan would have established an Advisory Committee on Breakthrough Drugs. This board would have been charged with examining new drugs and their prices in reference to a variety of prices charged in European nations. Initially, the group would only have had only an advisory role, but many believed that it would ultimately become a price setting body. The Medicare program would also have demanded rebates from drug makers based on prices in other nations. In tandem with these measures, after 1999, the government would have capped the price increases that insurance plans would have been permitted to the inflation rate. This provision would tend to force down the price of drugs even further, or exclude them from coverage so as to keep the premiums in line with the law. Many critics believe that these provisions taken together could have had a particularly

³⁴Donald Drake and Marian Uhlman. Making Medicine, Making Money, p. 18.

devastating impact on R&D, because of the power vested in government to heavily control pricing of new drugs.

There is no question that the mechanism behind the Advisory Committee was unwieldy. Also, since development of drugs is something of a lottery, the winners must make up for the losers. The argument that price controls will harm R&D is at least persuasive enough to strike fear in the hearts of those concerned about future R&D. When faced with diminished returns, the drug industry would have to look somewhere to cut costs and R&D may well be a first target. Part of the problem with price controls is that they are aimed at the most costly drugs, which are the drugs that usually bring in the largest profits to the drug makers. These highest grossing drugs are very often the most therapeutically innovative. Some drugs ultimately brought to market do not cover their R&D costs and it is the greater returns of the top tier of drugs that help fund the overall research efforts of drug companies.³⁵ The profits on breakthrough drugs thus tend to cover the R&D costs of all of the drugs which fail to make it to market, as well as the drugs that are marketed but are not terribly profitable. The problem is that if the price of any good is set by the government at a level *below* the price that would be set by market forces, the quantity of that good will be reduced. Since price regulation is designed ostensibly to drive prices *down*, there is a great concern that the reduction in quantity will come from diminished R&D rather than other drug company expenditures. One observer has argued that the mere threat of the Clinton Healthcare Plan caused a decline in research efforts. From 1981 until 1993, annual increases in the R&D budgets of the pharmaceutical makers averaged 11% per year. In 1994 and 1995, they dropped to 3% and 4% respectively. In 1996, after Congress had rejected the plan, without ever taking votes on it, R&D expenditures resumed the roughly 11% annual increases.³⁶ Pinpointing causation versus correlation is never easy, but the Clinton's proposal for price controls was the first in a generation and for a time, it looked like some variant of it might pass.

³⁵Henry Grabowski. Health Reform and Pharmaceutical Innovation, p. 15.

³⁶John Calfee. Prices, Markets, and the Pharmaceutical Revolution. (Washington, DC: AEI Press, 2000), p. 46.

A look specifically at the emergent biotechnology industry is also illustrative. Unlike industry giants like Pfizer and Merck, these are small companies that make even riskier bets. Although a few of these companies like Amgen and Genentech have blossomed into large players, most are small and operate on something of a financial shoestring. The risks that these companies take is predicated on the potential for a large reward in the form of high sales and profits. Thus, they are even more dependent on superior returns from a few blockbuster drugs since their costs and their failure rate is higher. Also, the reliance by biotech firms on external financing would make them susceptible to declining innovation in a world of price controls. The larger drug concerns do much of their R&D with retained earnings. As was argued earlier, the retained earnings would diminish under a price control regime. However, small biotech firms might see that it was even harder to attract external investment and financing when price controls would clip returns considerably.³⁷

Another way to look at the pharmaceutical industry is that the high costs of R&D are essentially joint costs. In particular, the costs of doing the research and developing the drug are the same regardless of how many people ultimately buy it. These are also sunk costs, in this case, because the costs are committed before the governments determine the price they will allow for a given drug. The reason why drugs are different than utilities is that the joint, sunk costs are global rather than local.³⁸ A utility has large sunk costs in its power plants and generating equipment. Yet such plants are located in every country, and the residents of that country pay rates that tend to pay off those sunk costs over time. Because drug makers are involved in a global business, it means that individual nations will try to drive prices down to the marginal cost of serving that nation, which essentially means the cost to cover manufacturing and distribution only. If every single nation set prices based only on marginal cost, there would be no R&D, because nobody would be paying for it.³⁹ One reason why price controls are attractive to governments from this standpoint is that they will

³⁷Henry Grabowski. Health Reform and Pharmaceutical Innovation, p. 19.

³⁸Patricia Danzon. Pharmaceutical Price Regulation. (Washington, DC: AEI Press, 1997), p. 7-8

³⁹Ibid., p. 9-11.

not reduce the supply of drugs on the market because price regulators do account for marginal cost. Thus they are unlikely to see the supply of drugs dry up nor are they likely to see any other near-term negative consequences. But since they do not allow for the joint costs, future developments will be impeded. One observer, Judith Wagner from the Office of Technology Assessment, puts it this way: "...drug companies have made substantial price concessions in countries representing a small proportion of the world market... [but] [I]f everyone were to pay those prices the worldwide revenues for some products might not be adequate to bring forth the products."⁴⁰

The principal concern with price regulation, of which the Clinton Healthcare Plan is but one example, is whether a company is likely to undertake risky and expensive research if a government agency and not the interplay of supply and demand will set the price of the drug. One can ask the question posed earlier: what is a fair price for a drug, or a fair price for anything for that matter? The price of most goods and services in the American economy is set by supply and demand, that is, the amount that people are willing to pay. The Clinton Healthcare Plan would use the prices deemed reasonable by foreign governments to set American drug prices. The relation to demand, or what people are willing to pay, was nowhere in the calculus. It would seem illogical to say that the fair price of a drug is not the amount that people are willing to pay, but rather what prices are charged in other countries, where it is the government that sets the prices. This problem of having U.S. prices set by foreign standards is one of the key issues in the price control debate. One pernicious result might be that the U.S. could watch prices in other nations, and negotiate with drug companies when those prices drop, creating some amount of opportunism.⁴¹ The aforementioned notion about the pharmaceutical industry being essentially a global business is noteworthy here. If the U.S., which is the only large nation not to regulate drug prices, were to do so, there would be no large market left for drug makers to recoup their R&D. Put another way, if every nation priced only at the cost of manufacturing

⁴⁰Robin Margolis, *Prescription Drug Pricing: Do Competitive Forces Operate in the Pharmaceutical Marketplace?*, 11 NO. 2 HealthSpan at 13.

⁴¹Henry Grabowski. *Health Reform and Pharmaceutical Innovation*, p. 22.

and distributing the drugs to that nation, without sufficiently accounting for the past R&D costs, the R&D would never be paid for. So, if the U.S.'s laissez-faire policy on drugs allows drug giants to recoup their R&D costs without negatively impacting Europeans and others, price restrictions here might reduce such R&D dramatically, since there would be no remaining large markets where such costs could be recovered.⁴² Even if one has difficulty accepting the argument that American consumers subsidize the R&D costs of price-regulated European consumers, it is still undisputed that R&D costs need to be borne by someone. And if the U.S. joined the Europeans in failing to adequately take them into account, they would not be paid for. Of course, the government could try to account for costs and R&D by requesting price and cost data from manufacturers. However, there is a great risk that such a system would become a slow, bureaucratic nightmare.⁴³ In addition to the diminished profits that price controls would bring, there would be great uncertainty surrounding price negotiations. Any strategy giving the government room to negotiate prices over long periods of time or any time throughout the lifecycle of a drug is likely to harm R&D, because the entire research environment will be unpredictable. So, whether one uses Bill Clinton's foray into price regulation as an example or not, the pharmaceutical manufacturers are likely to respond to legislative price controls with the same R&D based argument. The argument has its holes, but it is the industry's strongest one nonetheless.

The arguments on both sides are backed up by strong research and both also appeal to the emotional side of the public. When arguing that R&D will be reduced, the industry typically uses the tool of cross-national comparisons to show that regimes that have adopted price controls have substantially trimmed the incentives

⁴²John Wechkin, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents*, 5 PAC. RIM L. & POL'Y J. at 258.

⁴³John Calfee, *Prices, Markets, and the Pharmaceutical Revolution*, p. 52.

for developing new drugs. France arguably has the tightest price controls of any European nation. The French approach generally sets strict controls, and often the annual increases granted to drug manufacturers run below the general inflation rate.⁴⁴ Since the inception of these controls, it appears that the French drug industry has lagged behind those of other nations. The U.S., formerly a laggard in the development of beta blocking cardiovascular drugs, for instance, has risen to dominance, essentially reversing positions with France. One inference is that price controls have reduced incentives in those nations to research in this otherwise promising therapeutic area.⁴⁵

While the French tightly regulate price without more, Britain has developed a creative approach that does not hold down prices nearly as much, and encourages greater respect for the R&D needs of pharmaceutical firms. Their scheme provides for an R&D allowance of roughly 20% for each pharmaceutical firm. Although such government control may strike Americans as peculiar, the system clearly fosters greater innovation than the continental European regimes. Their industry is widely regarded as more innovative than those of continental European nations. Economists usually attribute this to the more generous consideration of R&D needs. For example, the British drug makers did much of the work in discovering beta blockers for cardiovascular ailments, and Zidovudine (AZT), the first major drug for HIV.⁴⁶ France and Italy, for instance, have contributed little in this area and both have stricter regulatory regimes. Although the British system protects large firms, the R&D allowance may not be enough to permit small companies to prosper, many of which develop the most innovative biotechnology drugs. The British system is superior to continental Europe's also because firms with more innovative drugs are permitted a greater allowed rate of return, thus spurring the search for genuine breakthroughs. As well, the U.K. system simply sets profit rates but allows

⁴⁴Baruch Brody. *Ethical Issues in Drug Testing, Approval and Pricing*, p. 239.

⁴⁵Robert Goldberg, *Policy Report No. 230* (visited February 14, 2000) <<http://www.ncpa.org/studies/s230/s230.html>>

⁴⁶Baruch Brody. *Ethical Issues in Drug Testing, Approval and Pricing*, p. 235.

otherwise free pricing thus reducing the uncertainty and administrative costs associated with a government board determining the price of every single drug. British drug firms spend more than twice as much on R&D relative to sales as other European countries. By contrast, during the 1980s, France and Italy began to see declining R&D relative to sales⁴⁷ France and Italy have produced a number of domestically marketed drugs, but no major global products since 1985.⁴⁸ The British system works better than most, but drug makers would likely point out that it is still not as effective as America's unregulated system.

It is clear from the British system that some international efforts at control are likely to be less harmful to R&D incentives than others. The German system is roughly set at a midpoint between the stringency of the French and the flexibility of the British. It is based on a "reference pricing" scheme which does not impose the stringent mandates of the French, but which does not grant R&D allowances like the British. In Germany, drugs are grouped into therapeutic blocks and prices are compared to others within that block. A reference price is then determined, most likely based on a lower priced drug within a given block. There has been great concern among German drug makers about this system and its effects on R&D, but few studies have explored the area since this reform is only a few years old. Nevertheless, German drug companies are not generally viewed to be as innovative as American ones. Finally, one can look at the developing countries to see the potentially deleterious effects that controls can take on R&D. Most international health experts believe that the reason why new drugs are not developed for conditions like malaria is because there is no profit in selling drugs to poor foreigners. This is undoubtedly part of the explanation. However, the fear that developing countries would implement compulsory licensing or price controls may have created a climate that inhibits the development of drugs for malaria, where an otherwise urgent need is present.⁴⁹ Presumably, if price controls diminished R&D, what might result is a situation where drug companies came to resemble the

⁴⁷Patricia Danzon. Pharmaceutical Price Regulation, p. 60.

⁴⁸Ibid., p. 62.

⁴⁹John Calfee. Prices, Markets and the Pharmaceutical Revolution, p. 48.

regulated public utilities of a generation ago, with limited but predictable profits and minimal innovation. The risk is that price controls might turn back the clock on America's already nimble drug giants. The cross-national studies do suggest some amount of risk to R&D when a nation adopts price regulation. The data also show some nuance. More flexible types of price regulation, such as Britain, appear more compatible with large scale R&D than the more stringent regulation of France and Italy.

When one compares the European system with the American system, it is clear that American drug makers have been more successful than most European nations. Few people agree on the reasons for this. The pharmaceutical industry believes the reason that American companies develop the largest number of innovative new drugs is because the U.S. is alone in the world in allowing the market to set the price of drugs. When compared to the Europeans mentioned in the previous paragraph, the differences are indeed striking. Between 1970 and 1985, by one estimate, the U.S. accounted for 43.4% of new drug innovations. One study suggested that in the 1990s American firms marketed 45% of drugs sold on a global scale.⁵⁰ As a general matter, the U.S. and U.K. discovered nearly 60% of all major internationally marketed drugs. Citing figures about American dominance in pharmaceuticals is both revealing and troublesome. The economic dominance exercised by the U.S. in many fields is likely to carry over into new drug development as well. The fact that a large number of new drugs are developed here is correlative with the light regulatory climate, but deriving any causal links between the two without more, is inaccurate. Still, drug companies have a point when they compare the European systems to that of the U.S. There are indeed serious shortcomings to price regulated regimes.

The issue of R&D incentives is largely focused on innovative or breakthrough drugs. Part of this is because

⁵⁰Robert Goldberg, *Policy Report No. 230* (visited February 14, 2000) <<http://www.ncpa.org/studies/s230/s230.html>>

using the argument that price controls will reduce the number of innovative life-saving drugs is something to which people respond. It certainly makes for appealing media “sound bites”. And many critics of the industry do recognize that it is costly to develop such drugs. Protease inhibitors for AIDS are a classic example. Yet there is another side to this issue. Namely, some argue that American drug companies exaggerate their R&D costs because many of the drugs brought to market are similar to other drugs on the market, rather than being truly innovative. These critics of the industry argue that drug companies pad the costs associated with developing innovative drugs with a healthy number of imitative “me-too” drugs.⁵¹ A whole host of the new drugs are mere chemical imitations of drugs already on the market. These drugs merely tweak the chemical processes of their competitors. By one estimate, 50% of drugs brought to market between 1980 and 1992 were imitative drugs.⁵² Once again, the anti-ulcer class of drugs is used as an argument. Once Tagamet, the breakthrough drug was developed by SmithKline, other drug companies looked for different compounds to block the same H2 receptor that Tagamet blocked. The patent restricted them to developing different compounds, but the drugs were therapeutically very similar. Developing another H2 inhibitor based on an earlier model was cheaper and easier than developing an innovative drug for dementia, for instance. Certainly, the drug companies very often do take the path of least risk and resistance.

There is no doubt that certain medicinal categories like antibiotics, cholesterol and anti-depressants have seen more than their fair share of drugs. Critics of the drug companies are right that these compounds are cheaper and less risky to develop. Yet, they fail to make one point. They often say, as will be seen later, that pharmaceutical markets are not competitive because they are dominated by patented monopolies.

The aforementioned Ceredase for Gaucher’s disease, and its obviously outrageous price, is the best example.

⁵¹Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN. J.L. & PUB. POL’Y at 91.

⁵²Robin Margolis, *Prescription Drug Pricing: Do Competitive Forces Operate in the Pharmaceutical Marketplace?*, 11 NO. 2 HealthSpan at 12.

Yet when market competition does prevail as in many cardiovascular and ulcer drugs, they attack drug companies for imitating their rivals. They are right to say that drug companies are often risk-averse when developing new compounds. However, using this as a sword to attack the drug companies, they should not be surprised when the drug companies turn around and use the same argument as a shield to show that many drug markets are highly competitive, not patented monopolies.

Even if American drug companies do make a large number of low risk imitative compounds and thus slightly exaggerate their R&D needs, systems that have adopted price controls seem to have created incentives to focus on imitative research even more than in the U.S. France, for instance, has some of the tightest regulation of drug prices anywhere. Some suggest that it is in societies like that where the bulk of the new drugs are imitative. The reason is that the price controls diminish the incentives for expensive research on breakthrough drugs, and instead push the drug companies toward less expensive, less risky, “imitative” drug research. These arguments are strong, but it is equally plausible that more lax standards of clinical testing for safety and effectiveness in Europe give rise to the large number of imitative drugs. Products that were clinically useless might come to market in nations without strong testing requirements, while the FDA would screen them out entirely.

The issue can be looked at another way. If the U.S. were to implement a form of price control, not only might R&D be impacted, but the market for new drugs might shift to “me-too” imitative drugs. Essentially, a pharmaceutical firm develops an R&D budget taking into account the increased expense of developing truly innovative drugs. As argued before, it is the prospect of huge financial payoffs that may encourage this dynamic research endeavor to take place. Not only might price controls reduce the overall amount of R&D but the lower cost and less risk involved in developing imitative drugs might lead them to become an increasing share of new drugs.⁵³ The systems that use reference pricing like Germany are likely to see a particular

⁵³Patricia Danzon. Pharmaceutical Price Regulation, p. 47-48.

form of damage to R&D. If the reference group is defined too broadly and it includes older less effective drugs, then the reimbursement price for the newer innovative drug will be based in part on those older drugs. Since these older drugs are likely to be cheaper, the cost of the innovative drug will be forced down without adequate recognition of its innovative properties. Again, a company under a reference pricing scheme might create an imitative drug to get a reimbursed price that covers its more minimal R&D rather than take the risks on an expensive new drug whose price might be set in relation to old drugs with only relative marginal efficacy. There is no doubt that price controls create major risks of creating an entirely imitative R&D schedule. In theory a price regulation regime might be designed to mitigate this by offering more generous allowances for innovative products over imitative ones. What seems to have happened, especially in Japan and France is that regulators do grant a higher price for *new* drugs, but without regard to their innovative properties. This has created further incentives to develop many new drugs that merely tweak existing drugs, so as to reap the benefits of the new drug allowance, but still not one that is generous enough to reward innovative R&D.⁵⁴ So many critics are right in saying that a host of the new drugs developed by American pharmaceutical companies are not innovative. However, in regimes with price controls, this “me-too” effect is even more pronounced, because price regulated systems create perverse incentives not to innovate, but to tweak the drugs of your competitors. When it comes to imitative drugs, it may be bad here, but its far worse elsewhere.

While acknowledging that developing new drugs is neither cheap nor easy, the response given by consumer advocates is typically that the pharmaceutical industry is one of the most profitable in the United States. They evince less sympathy for industry arguments about the cost of R&D or the high rate of failures for initially promising new compounds. The following comments from a prominent critic of the industry illustrate

⁵⁴Ibid., p. 51-52.

the political strains associated with this issue:

[S]o help me understand: Taxpayers fund much of the basic research

that produces new drugs. You are granted generous tax subsidies for

your own research. You charge outrageous prices to taxpayers to buy

your drugs. You tell taxpayers you can't do any more research if your

prices drop to the same levels as citizens pay in other countries in the

world. You devote huge amounts to promote lifestyle drugs. And you

earn windfall profits. . . Despite your well-oiled lobbying machine,

something will be done to bring down the cost of prescription drugs.⁵⁵

There are several studies that have been done which bolster the argument that the pharmaceutical industry is intensely profitable. The Congressional Research Service study found that the pharmaceutical industry averaged an after-tax profit of 17% on sales, as opposed to 5% for all other industries.⁵⁶ From 1980 to 1990 the American pharmaceutical industry had an average after-tax profit of 21.1% versus 11.9% for manufacturing industries.⁵⁷ The Staff Reports found that the average consumer goods company has a profit margin of 10.5%, while pharmaceuticals has a margin of 28.7%.⁵⁸ Whether measured by return on equity, return on sales or even gross profit margins, the industry appears to be among the most profitable among Fortune

⁵⁵Brown, Sherrod, *Dear Drug Company CEOs*, NATION, 11/01/99, pp. 6.

⁵⁶Daniel Greenberg, *Drug Pricing Powder Keg Stirs Up U.S. Health Care Politics*, LANCET, 1/8/00, p. 125.

⁵⁷Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN J.L. & PUB. POL'Y at 90.

⁵⁸Minority Staff Reports, *Prescription Drug Pricing in the Fifth Congressional District* (visited March 1, 2000) <http://www.house.gov/barrett/drug_company-profits.html>

500 companies. Yet there is another way to look at the industry. Others have argued that in research intensive industries such as pharmaceuticals, it is improper to use accounting-based measurements of returns and profits. Further, one scholar has argued that corporate balance sheets in industries with large R&D expenditures tend to understate the value of the company's assets and will thus give an artificially high rate of return.⁵⁹ When looking at *individual* returns on new drugs, the data show that they are just above the cost of capital, meaning that the returns cover R&D and some profit, but are much less inflated than other measures. Further, some analyses have determined that a majority of new drugs do not even cover R&D costs, thus showing a very skewed pattern of profits.⁶⁰ Particularly, a few blockbuster drugs must succeed to make up for the thousands that fail in pre-clinical and clinical trials.⁶¹ Finally, the very risks inherent in the pharmaceutical business would strongly argue in favor of higher rates of return there as opposed to safer businesses with fewer gambles on new products. Some of this data on the profitability of the industry may seem contradictory. Both sides of the debate, however, are correct. The pharmaceutical business is risky and most efforts to develop new drugs fail, and even many that succeed are hardly blockbusters. However, many drugs do succeed, and these pay for the failures. It is these successful drugs that make the industry so profitable. Whether one sees the industry as risky or profitable depends simply on what set of numbers the person is looking at.

What seems to gall consumer advocates even more is that some of this profitability is the result of government action itself. The patent system, and the monopoly grants that it engenders, will be explored in the next section. There are other examples of government presence. One is the R&D tax credit. Enacted in an effort to spur costly research in the hopes of future economic dividends, the pharmaceutical industry

⁵⁹Baruch Brody. *Ethical Issues in Drug Testing, Approval and Pricing*, p. 247.

⁶⁰Henry Grabowski. *Health Reform and Pharmaceutical Innovation*, p. 31.

⁶¹Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Ch. 1, ¶ 8 (visited February 27, 2000) <<http://www.cbo.gov>>

is a major beneficiary of this tax code provision. The Internal Revenue Code also grants a deduction to companies that establish manufacturing facilities in Puerto Rico. Again, the aim of this provision is not to benefit drug companies, but to stimulate economic growth in Puerto Rico. That goal has largely failed, but the pharmaceutical industry has made a tidy sum by relying on that deduction. American drug makers have received over \$10 billion in tax credits from 1980 to 1990 under section 936. The tax provision is geared to profit, not to actual job creation in Puerto Rico. In essence, the higher the profits, the greater the tax savings.⁶² Of course, blaming the pharmaceutical industry for taking advantage of generally applicable tax provisions seems wrong indeed. Certainly, these deductions and credits may represent “tax loopholes” or special interest legislation. If that is the case, then Congress ought to repeal them, not blame the beneficiaries. And if they choose not to repeal, then many other research-intensive industries should be blamed for taking advantage of them as well. Taken together, these tax preferences have tended to produce lower effective tax rates for drug companies than other industrial concerns.

Proponents of price regulation also argue that National Institutes of Health (“NIH”) and other government grants supply much of the research needed in the development of new drugs. In the debate over Medicare coverage of prescription drugs, House Democratic Leader Richard Gephardt argued that one-half of the research money is supplied by government grants.⁶³ Much of the basic research for Norplant, the contraceptive device was done by the non-profit Population Council, and yet the drug sold for four times more than in some European markets.⁶⁴ Research on the cancer drug levamisole was done by the Mayo Cancer Center when it was an animal drug and yet a year’s supply costs nearly \$1,500. Government labs did much of the initial research on AZT and still the price was set \$10,000 per year.⁶⁵ Government and academic researchers also perform much of the basic research that initially had scant commercial value. It is impossible to quantify

⁶²Donald Drake and Marian Uhlman. *Making Medicine, Making Money*, p. 57.

⁶³Tony Pugh, *Report on Drug Prices Reignites a Debate*, PHILA. INQUIRER, 11/4/99, p. 4.

⁶⁴Donald Drake and Marian Uhlman. *Making Medicine, Making Money*, p. 69.

⁶⁵*Ibid.*, p. 69-70.

the value of this basic research. Although drug companies do spend vast sums on R&D, they also get a fair degree of help from government, academia and the non-profit world. This is important because whenever government grants someone a benefit, there is a much stronger argument that they have the right to expect something in return. When the government research is added to the tax benefits and patent system, it is clear that drug companies are not doing everything on their own.

Finally, detractors of the pharmaceutical industry often say that drug prices are increased not to expand R&D, but to reap fat profit margins. They typically look to the fact that prices increase for drugs that have been on the market for many years and have already recouped their R&D costs. For instance, Dilantin, a drug for epilepsy which was introduced in 1953 has seen annual price increases of 11%. From 1981 to 1991 when general inflation rose cumulatively at a 50% rate, the price of Cogentin, a Parkinson's Disease drug approved in 1954 rose 208%.⁶⁶ These increases may well be egregious. However, the principle enunciated earlier is that the drug companies reap profits off of a few drugs to cover their overall R&D costs. Thus, it should come as no surprise that once a drug reaches the break-even point, the company wants to continue to make money from it. These profits will be used for R&D on *other* drugs, as well as other expenses. The R&D argument made by the industry may or may not be overwrought, but any analysis that focuses on the price of one drug to the exclusion of the overall nature of R&D is misleading. While this section explored the ways in which the pharmaceutical *companies* are similar or different from others, the upcoming subdivision examines the extent to which pharmaceutical *markets* are similar or different from others.

IV. COMPETITION IN PHARMACEUTICAL MARKETS

⁶⁶Ibid., p. 61.

Another argument made by advocates for control has been superficially touched already: the lack of a free market in pharmaceuticals. A competitive market in traditional economic theory is one with many producers and many consumers. The principle of such markets is that the equilibrium price will be driven to the lowest level consistent with supply-demand constraints. However, it is not clear to industry opponents that the market for prescription drugs represents a competitive and free market in any such way. The reason is that in addition to the expectation of large profits from sales of a blockbuster drug, the pharmaceutical firm also seeks patent protection for the new medicine. A comprehensive analysis of the economics of patent markets is not necessary to an understanding of the fundamental argument made by consumer advocates. Namely, the fact of patent protection for a number of important medicines means that there is something less than a free market operating with respect to many prescription drugs. Basic understanding of economics dictates that the lack of a free market means that drug companies can raise prices above the level that they could if there was a competitive market.

The Orphan Drug Act is a good example. This law, designed to spur research that might not otherwise be profitable, helps to create a market for treatments for rare diseases. The most valuable part of the law is the exclusive marketing provisions, which essentially grant a company a monopoly power over their drug for a period. These provisions have resulted in a marked increase in the development of orphan drugs. This monopoly position, coupled with the absence of price regulation, has led to very high prices for the so-called “orphan drugs”. The Orphan Drug Act has also created some controversy because of its generous allowances to drug makers. An attempted revision to limit the exclusivity provisions to sales up to \$200 million failed to make it into law. A true free market then does not exist with regard to this small subset of medicines that are orphan drugs. Outside of the orphan drug context, the effect of patents on competition is still substantial. The value of such patents is best shown by the measures taken by drug makers to have those patents

extended on individual drugs. Because the patent time begins running before the drug is actually approved, pharmaceutical companies have attempted to extend the patents beyond the initial grant as compensation for this fact. It has been estimated, for instance, that the nineteen month patent extension on the Zantac ulcer drug resulted in an additional \$1.1 billion in revenue to its manufacturer, Glaxo-Wellcome.⁶⁷ Canada has for a long time had a system of compulsory licensing of patents, which give generic drug makers the right to develop competing formulas very quickly. Not surprisingly, few breakthrough drugs are developed in a regime so inimical to fostering innovation.⁶⁸ The American patent system helps to foster innovations that might otherwise not occur. These same patents also undermine market competition by ensconcing dominant players in a dominant position. The extent to which the patent grant needs to be mitigated by other policies is an important piece of this debate.

The issue of patents dovetails with the discussion of price controls. In exchange for a government grant of patent protection, the government would expect limits on price increases in exchanges. There are strong arguments against this, and it relates to the previous discussion of R&D. For one, the principle behind patent protection is to encourage innovation, and protect it once it has produced something of value. In effect, to superimpose a price control on top of a patent is to diminish the value of the patent itself. The risks taken in the research process are predicated not only on being able to reap profits through freedom of pricing, but also through the mechanism of a patent. Eliminating freedom of pricing means that the grant of a patent would be at least slightly diminished. Although the patent would grant some amount of exclusivity, the government would control the prices charged in a way that it does not today. In some cases, where there is

⁶⁷Common Cause, *How Special Interest Money Hurts the American Consumer* (visited February 26, 2000) <<http://www.commoncause.org/publications/pocketbook2.htm>>

⁶⁸Baruch Brody, *Ethical Issues in Drug Testing, Approval and Pricing*, p. 240.

no competition in a particular market, as in the case of rare diseases, such price regulation would be more appropriate.

So, consumer advocates argue that a market-based profit cannot be allowed in the pharmaceutical arena because a free market does not exist, due in large measure to the heavy use of patents. However, there is far from universal agreement that competition is lacking in the pharmaceutical industry. New drugs approved in 1991-92 were about 14% cheaper than bestsellers already on the market. Four new ACE cardiovascular drugs launched in 1991/92 had prices more than one-third less than those already on the market.⁶⁹ The market for cholesterol drugs is also illustrative. The breakthrough drug was Mevacor, introduced in 1987. The next drug to follow, Pravachol, was priced lower. And the next drug, Zocor was priced lower as well. Even with patents then, there are a variety of treatments in the cholesterol category from which to choose. Because of the possibility of substituting one drug for another, especially in areas such as antibiotics, anti-hypertensives and anti-inflammatories, HMOs are able to foster further competition.⁷⁰ There are, for instance, eight patented similar ACE inhibitor drugs to treat hypertension and four drugs to treat ulcers that are nearly interchangeable.⁷¹ Robust competition may, in fact, prevail in many markets, notwithstanding the patent system. Drug markets are more than a series of patent-protected monopolies where drug companies set any price they wish. However, the amount of the competition varies temporally, namely, there is usually more competition after a patent expires. And finally, the level of competition varies across product classes, with some like the aforementioned cardiovascular drugs being quite competitive while the market for treatments for Gaucher's disease is practically a government sanctioned monopoly.

⁶⁹Robert Goldberg, *Policy Report No. 230* (visited February 14, 2000) <<http://www.ncpa.org/studies/s230/s230.html>>

⁷⁰Michael Weber, *Impact on the Pharmaceutical Industry of Changes in the American Health Care System*, 24 SETON HALL L. REV. at 1293.

⁷¹Shawn Tully and Joyce Davis, *The Plots to Keep Drug Prices High*, FORTUNE, 12/27/93, p. 120.

The reasons behind this competition are tied to the patent system itself. While patents are invaluable to drug companies, they do not grant total monopoly power as some consumer advocates suggest. A drug patent applies to a specific chemical or production process, and different drug makers can patent similar drugs based on the same underlying medicinal principle. These “me-too” drugs can create some degree of imperfect competition that diverges from the results that monopoly theory would predict. The case of the anti-ulcer therapeutic segment is instructive. Tagamet was the first drug to block an H2 receptor, which regulates the production of stomach acid. Within six years a second H2 drug, Zantac was approved. Six years after that, two more H2 blockers were approved. All of these were patented, but all were approved because they used slightly different mechanisms for blocking H2 receptors. In fact, it is not unusual for a breakthrough drug to have only one to six years of true market exclusivity before it faces stiff competition.⁷² The CBO study also showed that even after a “me-too” enters a particular therapeutic segment, the price of the breakthrough drug (or the first drug in that therapeutic segment) continues to rise faster than inflation, but not as fast as those therapeutic segments with no competitors.⁷³ The time it takes to establish competitor drugs has also been steadily declining. For instance, the first “beta-blocker” was introduced in 1965, and it did not face a major competitor until 1978. By contrast, the arthritis drug Celebrex was without competition for only a few months, and the first protease inhibitor for AIDS had a similarly short grace period.⁷⁴ Branded drugs are facing stiffer competition in a shorter period of time. Some form of imperfect competition then, appears to result when more than one brand name drug competes against one another. Consumer advocates remain unconvinced that real competition exists. The same ulcer market used by industry to show that competition is strong, is used by consumer advocates to demonstrate that while some amount of *product* competition may prevail, little *price* competition exists. After Zantac was introduced to compete with Tagamet, the

⁷²Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Ch. 3 ¶ 22 (visited February 27, 2000) <<http://www.cbo.gov>>

⁷³*Ibid.*, ¶ 32

⁷⁴John Calfee, *Prices, Markets and the Pharmaceutical Revolution*, p. 20.

prices of both drugs rose after a year. When Axid and Pepcid later came on the market, they priced their drugs higher than Tagamet, and did not lower them since.⁷⁵ There were four similar drugs from which to choose, but price cutting was less than spectacular in the view of consumer advocates. However, the price of the original drug in the class, Tagamet, might be priced even higher today in the absence of having three other similar drugs from which to choose.

A patent is indeed one of the most insurmountable entry barriers an antitrust scholar or economist could imagine. Even assuming competitive pharmaceutical markets, any argument about patents and competition can only be sound when one looks at competition *during the life* of the patent. Upon expiration, the generic drug makers emerge to pose a much fiercer brand of competition. In fact, this is not just competition for the branded drugs; it is often a force that decimates. By some estimates, generic introduction reduces the market share of the branded drug by 35% in the first year and by 50% after two years.⁷⁶ When critics of the industry make claims about the anti-competitive nature of pharmaceutical markets, they typically overlook the influence of generics. And yet the role of generics has steadily increased. The Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) is the most current statement on this issue. This legislation allows generic drug companies to begin making products before the patents expire on the branded drugs. In exchange, it provides patent extensions to certain drugs. The law also eliminates the need for generics to satisfy rigorous FDA standards ordinarily applied to branded drugs. Generics need only show “bioequivalence”, namely that the active ingredient is released and absorbed by the body at the same rate for the generic drug as for the branded drug.

The results of generic competition have been profound. From 1984 to 1996, the market share of generic drugs

⁷⁵Donald Drake and Marian Uhlman. *Making Medicine, Making Money*, p. 10.

⁷⁶Donald Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3-FALL KAN. J.L. & PUB. POL’Y at 94.

increased from 18.6% to 42.6%. Essentially, a branded drug maker knows that R&D expenditures need to be recovered rapidly, that is, during the period of patent protection. After that point, their products face stiff competition from generics. Since the Hatch-Waxman Act, the average length of time between the expiration of a patent and generic entry in that market has dropped from three years to a few months.⁷⁷ By 1992, 72% of drugs moving off patent encountered generic competition within eighteen months. Since generics are unquestionably cheaper than branded drugs, some competition is present once a branded drug loses its patent protection. That competition is likely to be enhanced even further when there are numerous generic makers in the market for a single drug. CBO estimated that if each generic prescription had been filled with the branded counterpart, Americans would have spent an additional \$8-10 billion through retail pharmacies alone. The discounts on branded drugs given to large purchasers are also increased when those drugs face generic competition.⁷⁸ Though generic drugs do help foster competition, there is debate about the extent of that competition. Even after Hatch-Waxman, many patients use branded drugs where generics are otherwise available. It may also be the case that the pharmaceutical makers have increased the cost of branded drugs to compensate for the revenue lost to generic drugs in the wake of Hatch-Waxman. Nevertheless, even if the price of branded drugs continued to rise, one can say that it is the fact of having a therapeutic alternative that provides the necessary competition. The Hatch-Waxman Act clearly has not had a deleterious impact on R&D. R&D rose between 1985 and 1995 as a percentage of brand name drug sales from 15.1% to 19.4%.⁷⁹

The issue of patents is central to the debate over prescription drug prices because in the absence of a patent, prices would be lower. Certainly, nobody has argued for scrapping patents on pharmaceuticals, but some

⁷⁷Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Ch. 4 ¶ 5

⁷⁸*Ibid.*, Ch 3, ¶ 69.

⁷⁹*Ibid.*, Ch. 1, ¶14

have proposed a regime of compulsory licensing. This is a form of government control and analyzing its effects at this point is helpful in underscoring why patents are just as central to the preservation of R&D as the freedom to price. Compulsory licensing proposals typically require the maker of a branded drug to license the patent to competitors if prices increase at a rate greater than inflation or beyond some other indicator used, depending on the specific bill.⁸⁰ These bills are basically price controls in a more disguised fashion, as they require that certain prices or conditions are met, or the drug faces the devastating effect of generic competition before the normal expiration of the patent. In Canada, for instance, the government had required compulsory licensing without regard to prices charged, but repealed that system after the enactment of the North American Free Trade Agreement (“NAFTA”).

The potentially negative impacts that compulsory licensing can have on R&D are basically the same as the effects anticipated by price controls. Namely, if the profits during the period of patent protection are limited by price controls the ability to recover R&D expenses and make a profit will be harder than under the current regime. It will, though, certainly create a climate of uncertainty for drug makers, which itself might be an undesirable outcome. The results, due to the lag time between research and product introduction, mean that the answers may not be known for many years. First, a drug maker might focus on developing those drugs that would not be subject to a compulsory license. Breakthrough drugs would be avoided because licensing would be certain to occur there, whereas “me-too” imitative drugs would be encouraged because compulsory licensing would be unlikely there. The companies may simply reduce research altogether, by focusing on marginal improvements on research that they had previously done.⁸¹ Yet another problem with compulsory licensing is that companies that do not undertake the expense and time of doing the R&D reap the rewards of that research when they receive the license. In addition, they can charge an even lower price

⁸⁰Brown, Sherrod, *Dear Drug Company CEOs*, NATION, 11/01/99, p. 6.

⁸¹Alan Fisch, *Compulsory Licensing of Pharmaceutical Patents*, 34 JURIMETRICS J. at 312-313.

than the innovator-company because they do not have to recoup their investment in R&D.⁸² The company that did undertake the costly R&D is faced with a cheaper drug, which may cause it to lower its price below the level at which it can recoup its own investment in the drug. This results in a vicious circle. Certainly patents do change the complexion of a given market, by granting preferential treatment to innovators. These grants are essential to innovation. Consumer advocates however, will continue to mention patents as a cause of high prices and use this as an argument for some government control over the holders of those patents.

V.

PHARMACEUTICAL MARKETING: CORPORATE WASTE?

A generation ago a pharmaceutical company and a consumer products company had little in common. One engaged in mass retailing aimed at the expanding middle classes, while the other was significantly more arcane to the average person. Then came the advertising revolution. Ultimately, the FDA gave pharmaceutical companies greater ability to advertise and market their drugs directly to consumers. The proliferation of television and magazine spots for allergy, hair replacement and cholesterol treatments is one outgrowth of this phenomenon. At this point, it may not be clear why advertising is relevant to a discussion of drug prices. The most straightforward argument made by proponents of price regulation is essentially that these large sums spent on advertising and marketing actually drive up the cost of drugs. Their arguments are directed at both direct-to-consumer advertising, as well as detailing (industry jargon for marketing targeted to health care providers).

⁸²John Wechkin, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents*, 5 PAC. RIM L. & POL'Y J. at 242.

Advertising has long been recognized as an essential element in a free market economy in terms of ensuring allocation of resources in an efficient manner. With pharmaceuticals that should be no exception, but consumer groups nonetheless see the money as waste. By one estimate, about twenty cents on every dollar spent on prescription drugs pays for advertising, promotion and marketing.⁸³ There is roughly one pharmaceutical salesperson for every twelve prescribing doctors in the country. Another study suggests that over \$1 billion was spent on direct marketing in 1997 and 1998, and the majority was directed to consumers.⁸⁴ Even more striking is data showing that drug companies spend about 16% of their budgets on R&D, but 20% on promotion. Pharmaceutical companies direct their advertising to consumers and physicians. Drug companies have also directed some of their marketing heft toward HMOs and hospitals. This effort has been designed largely to ensure that HMOs include their drugs on their formularies, which are lists of drugs for which they will reimburse patients. With cholesterol, for instance, there may be a variety of similar drugs for which the HMO might reimburse at its lowest and best price. The makers of the major cholesterol drugs will do a great deal of detailing to ensure that the formulary chooses their drug over those of their competitors. The evolving relationship between HMOs and drug companies will be explored in the next section.

The concept of drug ads is obvious: to increase physician and patient awareness and demand. The first argument made against prescription drug advertising is that money spent on advertising could be returned to consumers in the form of lower prices. Opponents attack both direct-to-consumer advertising as well as the physician detailing. When drug companies argue that the high cost of R&D necessitates high prices, many consumer advocates point out that the 20% of drug company budgets spent on marketing demonstrates that there is more than enough room for R&D and cutting prices.

There is a deeper criticism typically leveled at advertising and marketing prescription drugs. Specifically,

⁸³Donald Drake and Marian Uhlman. *Making Medicine, Making Money*, p. 27.

⁸⁴Health Insurance Association of America, *Prescription Drugs: Cost and Coverage Trends* (visited February 25, 2000) <<http://www.hiaa.org/news/news-state/prescriptiondrugs.htm>>

some believe that marketing to physicians and consumers creates a form of “brand loyalty”, so that other brand-name drugs that may be cheaper are avoided. Worse, this brand loyalty may lead doctors to avoid recommending generic drugs when they are available.⁸⁵ Finally, the advertising may lead doctors to rely on prescription drug treatments when cheaper and perhaps safer alternatives are available. The advertising encourages doctors to prescribe drugs with which they are familiar, with little regard for price. The patient pays the bill on the drug selected by the third party doctors. The problem is likely to be even worse when insurance covers the drug, because then there will be practically no incentive to choose a cheaper alternative. To some extent this argument is more sophisticated than the “consumer surplus” argument. It is almost as if doctors and their patients are being dragooned into buying more costly drugs because advertising creates this brand loyalty, which closes out efforts at substitution of cheaper alternatives. Sometimes the brand loyalty effect will influence the patient to demand a certain drug. When a patient sees an ad for Allegra, they may demand that drug over a cheaper and equally effective alternative. The same influences may lead a doctor to prescribe Allegra instead of another allergy drug. When a doctor prescribes a certain drug, the patient may feel quite uncomfortable questioning the doctor’s choice, for a variety of reasons. This would tend to lock in the brand loyalty effect. And indeed, some such attacks have been leveled at the physician detailing. In fact, Abbey Meyers of the National Organization for Rare Disorder (“NORD”) argues essentially that point. She maintains that since it is largely doctors who choose the drugs for their patients, the drug companies spend vast sums to compete for their loyalty. She believes that the fact of doctor selection of the product undermines the extent to which the pharmaceutical markets are competitive and on top of that huge sums are wasted on gaining this physician loyalty.⁸⁶

The reasons for detailing to physicians is partly a recognition that no doctor can be aware of every drug

⁸⁵Donald Drake and Marian Uhlman. *Making Medicine, Making Money*, p. 33.

⁸⁶Robin Margolis, *Prescription Drug Pricing: Do Competitive Forces Operate in the Pharmaceutical Marketplace?*, 11 NO. 2 HealthSpan at 14.

on the market and the targeted efforts by drug companies will educate doctors about a particular product. Detailing can involve distributing anything from educational materials to golf balls and playing cards. Many argue for restrictions on detailing, saying that there is little tangible benefit to mitigate all of the negative aspects of this practice. There is some support for the notion that physicians and other health care workers find detailing to involve little education and largely salesmanship.⁸⁷ It certainly is hard to see how a drug company salesperson could objectively inform a doctor about a drug without crossing the line into salesmanship. If the educational value of such marketing is minimal, then the case for restrictions becomes somewhat stronger.

The “consumer surplus” argument is relatively simple, but the “brand loyalty” issue is more complex, and little research has explored it. A recent study did examine the effects of advertising on the market for hypertension treatments. It found that price advertising in competitive markets generally increases competition while *non-price* advertising might limit competition by increasing brand loyalty.⁸⁸ This was one of the first studies to specifically link advertising with the price elasticity of demand for a given drug. The study found that heavy detailing makes sales less responsive to price and leads to higher prices generally, at least in the hypertension segment.⁸⁹ Since the bulk of drug advertisements completely sidestep the issue of price and instead focus on the benefits of the brand itself, this would seem to suggest that pharmaceutical marketing is fostering brand loyalty more than robust competition. Given the importance of drugs to most people, advertising and marketing are likely to be viewed as forces that push up prices with few countervailing benefits.

It is certainly true that banning or dramatically restricting prescription drug advertising and marketing *could*

⁸⁷John Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry*, 42 J.L. & ECON. 89, 113.

⁸⁸*Ibid.*, p. 89-90.

⁸⁹*Ibid.*, p. 112.

represent a consumer surplus or could otherwise lower drug prices by reducing the “brand loyalty” effect. Such policies would not be without precedent. The British system of drug regulation has adopted a form of such regulation. Just as the British government grants an R&D allowance to drug companies, so too there is a marketing allowance. It is noticeably more restrictive than the marketing budgets of American drug companies. However, these policies necessitate a level of oversight of private industry that would be highly unusual to most Americans. Nevertheless, the possibility of restricting drug advertising and marketing is about as contentious as every other issue relating to drug prices.

The primary response is that many observers believe that prescription drug advertising and heavy marketing are positively good things. For one, the additional choice given to consumers may, in fact, *promote* competition among similar drugs. By arming a patient with the knowledge that allergies can be treated with Claritin, Allegra or Zyrtec, it is not just the doctor who can make the decision. Competition among different brands might easily lead to competition based on price. This might be especially true with garden-variety illnesses like acid reflux disease. If Pepcid, Tagamet and Axid are substantially the same, informed consumers might lead to price *cutting* that would otherwise be nonexistent in a regime that restricted advertising. Measuring the competitive effects is very difficult and little research has explored this area. Usually the industry points out the large number of drugs in a particular therapeutic class and leaps to the conclusion that advertising must increase competition among those drugs. The argument that advertising and marketing prescription drugs reduces costs is hard to make out, but the informational value of advertising is a much stronger point. Advertising does not simply create brand awareness, but it can also create awareness of medical conditions themselves. The clot-buster tPA, which can reverse the effects of stroke in the earliest moments has been heavily advertised, which may have helped in getting people to recognize the symptoms of strokes them-

selves.⁹⁰ Even the study exposing some of the negative consequences of advertising anti-hypertensives, acknowledged that detailing may increase awareness of *diseases* as well as drugs.⁹¹ Thus there are some benefits to advertising drugs, at least on informational grounds if not on price grounds.

The other aspect of the consumer advocate argument is also fraught with some problems. When presenting a prescription to a pharmacist, the patient is usually asked if he or she desires a generic equivalent. All of the advertising in the world directed at a doctor will not be able to insert them into every pharmacy and prevent a patient from purchasing the generic equivalent. Physician detailing then, only goes so far. While advertising might push branded drug prices up, generic alternatives remain to supply competitive pressures. The arguments made against heavy promotion by pharmaceutical salespeople also suggest that doctors will be completely insensitive to cost and prescribe drugs where they would not be needed. This assumption may be true, but it does not fully account for some recent developments in the health care delivery system. Specifically, the HMOs have forced increasing cost savings and have placed greater scrutiny on the sort of unquestioned health care expenditures that governed only a few years ago.

Even if prescription drug marketing does increase overall costs, there are strong arguments that consumers should be entitled to that information anyway. What makes the advertising debate difficult is one fundamental truism of advertising generally. That is, advertising any product does tend to stimulate demand. If it did not, it would have vanished long ago. Advertising also can increase competition, because it brings markets closer to the ideal of perfect information, where more informed decisions can be made. To argue for a restriction on drug advertising, one must believe that prescription drugs are fundamentally different from

⁹⁰John Calfee. Prices, Markets and the Pharmaceutical Revolution, p. 28-29.

⁹¹*Ibid.*

other consumer products. That is not such a difficult argument to make. It is also not terribly difficult to accept that marketing increases drug prices. Even assuming that it does, one must still get to the point of being willing to deny consumers the benefits of that information.

VI.

AN ALTERNATIVE APPROACH: THE MARKET

The most striking way to frame this debate is between price controls and *laissez-faire*. The U.S. has largely selected the latter approach, if for no other reason than legislative inertia. In the first parts of this paper, industry supporters argued against price controls and restrictions on advertising. Their approach, however, is not only defensive; in fact, they have asserted a vigorous offense as well. Their solution is to harness the current transformations in health care delivery so that *markets* can bring down drug prices. The main such approach is predicated on the power of hospitals and especially HMOs to negotiate lower prices on drugs for their patients. Not only is such market-based cost cutting desirable, according to many observers it is happening everywhere.

The rise of managed care and large HMOs with negotiating leverage has been able to force large discounts on the price of drugs used by their patients. Hospital mergers have increased concentration on that side of the business as well, thus increasing leverage relative to the drug companies. With a variety of different types of health plans from which to choose, consumers can have the power to choose lower cost plans which force down drug prices even more. This argument is aimed at the heart of why prescription drug prices, and health care costs overall, are so high. Namely, the problem of “moral hazard” engendered by third-party payment.

When one purchases an automobile, the cost is fully borne by the consumer. Thus, there is an incentive to bargain for the lowest price. However, specific drugs are chosen by doctors and often paid for by insurance companies with little active bargaining by the patient. When insurance companies pay, the impetus for the patient to bargain is often absent. In fact, there may be the overarching incentive to take unneeded drugs when other approaches may work as well. By placing power in the HMOs to negotiate directly with the drug companies, prices are likely to come down since those HMOs ultimately pay the bills. The moral hazard problem can be trimmed considerably if this process is allowed to flower.

This proposed solution to the problem of high drug costs is not without its detractors. The main reason is that the lower prices that HMOs receive are not given to individual consumers; instead what results is a bifurcated pricing structure. It is the very fact of lower pricing to health maintenance organizations (“HMO’s”) and large hospitals on the one hand and higher prices to individuals that has raised the ire of many of the industry’s opponents. Because of this, some members of Congress have advanced proposals to ban the differential pricing. These would essentially impose uniform prescription drug pricing. Representative Tom Allen, (D-Maine) has introduced such legislation in the House of Representatives, and Senator Edward Kennedy, (D-Massachusetts) has a companion bill in the Senate. Differential pricing is in one way a smaller debate within the larger debate about price controls. Such differential pricing is a market-based alternative to bring down the cost of drugs for large numbers of people. Yet industry opponents like Tom Allen and Ted Kennedy view it as another example of drug companies treating consumers unfairly.

It is worth exploring for a moment how these types of proposals arose. For one, they are not as far-reaching as price controls or single-payer type health care reforms that incorporate prescription drug benefits. They appear to represent an incremental approach, rather than a revolutionary one. They also seem to be enforcing

rules of “fair play” in the marketplace, in that they require the small consumer to be treated similarly to the large HMO. It may simply be that they are more politically palatable. There are numerous criticisms that have been leveled at these legislative proposals and that criticism is related to the importance of such bargaining leverage in bringing down drug prices. One argument against Allen-Kennedy is that by eliminating the differential pricing, *all* drug prices will gravitate to the higher price charged to individuals rather than the lower price charged to large buyers like HMOs.⁹² This is certainly the lesson from the 1990 Medicaid reforms. In that case drug makers were required to rebate to Medicaid an amount based on the lowest prices they charged other purchasers. This was designed to save money for the Medicaid program and it was included in the 1990 omnibus budget package, whose primary purpose was to reduce the then-ballooning federal budget deficit. Incidentally, it is the same “rebate” concept that President Clinton hoped to apply to Medicare in his health care proposals in 1993. These 1990 Medicaid reforms instead resulted in increased prices or at least reduced discounts granted to other non-government purchasers. Specifically, between 1991 and 1993, the average discount given to HMOs declined from 24.4% to 14.2%.⁹³ After the Medicaid reforms in 1990, prices charged to other agencies like the Defense Dept. and the Veterans Administration rose. The largest HMO trade association claims that its costs for drugs rose 20% from the time of the reforms until April 1991.⁹⁴ So even if Medicaid got the “best price” after 1990, that best price was not nearly as good as it used to be. There is every reason to believe that requiring that drug companies charge private consumers the same low prices that they charge HMOs will only result in that single price going up, thus helping consumers only minimally and increasing the drug costs for HMOs. These results from the 1990 reforms may increase the animosity that many people have for the drug companies, but those were the results nonetheless.

The other argument against Allen-Kennedy, which is really an argument *for* disparate pricing, is far more

⁹²Kenneth Elzinga and David Mills, *The Distribution and Pricing of Prescription Drugs*, INTERNATIONAL JOURNAL OF THE ECONOMICS OF BUSINESS, Nov. 1997, Vol. 4, p. 237.

⁹³Patricia Danzon. *Price Comparisons for Pharmaceuticals*, p. 45.

⁹⁴Donald Drake and Marian Uhlman. *Making Medicine, Making Money*, p. 48.

important. To understand it, one must grasp the fundamental market relationships between HMOs and pharmaceutical companies. The HMOs do not simply purchase drugs and hand them out to those whose medical bills they pay. The HMOs can, in fact, *shape* demand for certain drugs and hence, the relationship between HMOs and drug companies is more symbiotic than that between the drug companies and smaller purchasers, like individuals or small pharmacies:

Drug discounts are given to these institutions for exerting influence over physician prescribing behavior. In other words, hospitals and managed care organizations exact discounts on prescription drugs from pharmaceutical manufacturers by inducing competition among therapeutically equivalent drugs for the en masse prescriptions of their patients. This interpretation explains why retail drugs stores do not receive the same discounts on prescription drugs. Intervening to influence the prescription decisions of physicians is not the same thing as dispensing prescription drugs, which is what drugstores do.⁹⁵

This explanation seems to justify arrangements that increase drug company profits by increasing the use of their products. HMOs use “pharmacy benefit managers” (“PBMs”) that have drug formularies. Doctors who are either employees of an HMO or are under some contract with them are strongly encouraged to use the drugs on the formularies. Their compliance with this regime is monitored periodically. Consumers are encouraged through the premium structure to abide by the formularies. HMOs often charge beneficiaries more for the use of branded drugs, thus encouraging generic substitution, which itself cuts costs. The degree of restrictions varies across plans. Some use closed formularies, where beneficiaries must pay the total cost of the non-formulary drug. Others used incentive-based formularies, where only part of the cost must be borne by the patient.⁹⁶ The concept of variable co-payments, that is HMOs charging different amounts

⁹⁶General Accounting Office, *Impact of HMOs Use of Formularies on Beneficiaries*, § 1.

for generic, branded or formulary and non-formulary drugs has also increased markedly in recent years. In 1996, 53% of HMOs had some form of variable co-payment; that number increased to 86% by 1999.⁹⁷ These arrangements are growing rapidly. In a comparison of prices charged to HMOs and prices charged retail pharmacies, the GAO found a 10% price difference for over one-third of the drugs examined.⁹⁸ The drug companies benefit from these arrangements because although they receive lower prices when the insurance companies force down costs, this is offset by the higher volume purchased by the HMOs as well as the guarantee that something approaching a certain minimum will be purchased.

There is no doubt that such discounts can be substantial. By one estimate, the use of HMOs and PBMs has cut drug costs by 30% in some health plans.⁹⁹ But is this good for consumers? Perhaps, for the members of a given HMO which receives cheaper drugs. If those patients have access to cheaper overall insurance premiums (due in part to the cheaper drugs they receive), their overall cost of receiving health care services ought to be lower. That is, if there are two therapeutically equivalent drugs, then the repeated use of Drug A over Drug B can cut costs because Drug A is sold in bulk, in exchange for the discounts. The rapid growth of these plans may or may not show that their cost-cutting role has pleased consumers. In most cases, these HMO formularies are consistent with consumer choice. In a comprehensive survey, in two of the most frequently used classes of drugs, most HMOs had between 12 and 22 antidepressant drugs and between 30 and 78 different anti-hypertension drugs.¹⁰⁰ In the second section dealing with drug prices, it was argued that accounting for drug costs in a vacuum without regard to the surgical treatments for which they substitute was unwise. The issue of global or component budgeting was also discussed. This part of the discussion, on market-based innovations does show that HMOs can be more effective in recognizing these

⁹⁷Ibid.

⁹⁸General Accounting Office, *Prescription Drug Pricing: Implications for Retail Pharmacies*, § 2.

⁹⁹Patricia Danzon, *Pharmaceutical Price Regulation*, p. 29.

¹⁰⁰General Accounting Office, *Prescription Drug Benefits: Impact of Medicare HMOs Use of Formularies*, § Letter 3

substitution effects than government regulators. HMOs typically look for the most cost-effective approach to solving a given health problem. They are unlikely to make the mistake of sending someone for an expensive ulcer surgery when a cheaper drug alternative exists. In this sense, the market can in many cases efficiently allocate limited health care resources in a way that governments often fail to do.

Retail drug stores are incapable of engaging in this sort of demand shifting, as they merely dispense the customer's requests. They are simply unable to pressure doctors or patients to change a prescription to another drug on a formulary that may be cheaper. Underlying the Allen-Kennedy proposals is the sense that individuals outside the HMO network are paying more than they would in the absence of the deep discounts to HMOs. Yet many observers believe that this sort of differential pricing does not lead to customers outside the HMO network to pay more than they would in a world without the discounts to large purchasers. Some others argue that disparate pricing actually results in *reduced* prices to those individuals purchasing drugs outside of the network. The economics is daunting, but the basic idea is that when hospitals and insurers purchase at discounts, the market essentially becomes bisected between them and individual consumers. The pool of individual customers is more price sensitive (in part because many do not have prescription drug insurance) than the market would be when all buyers are included. Hence, drug companies might tend to discount to the individual purchasers so as to avoid losing sales to this more price-sensitive group.¹⁰¹ All of this research is cold comfort to proponents of Allen-Kennedy and other legislative solutions, because while these studies may attempt to *justify* the disparate pricing, it is the disparate pricing itself which they view as the problem. Although there may be fairness problems with charging two customers entirely different prices, in this case, there may be efficiency losses to uniform pricing, by undercutting the progress made by HMOs in reducing health care expenditures. What would likely result based on the 1990 reforms is that

¹⁰¹Kenneth Elzinga and David Mills, *The Distribution and Pricing of Prescription Drugs*, INTERNATIONAL JOURNAL OF THE ECONOMICS OF BUSINESS, Nov. 1997, p. 287.

the discrepancy in pricing would evaporate, with no greater discounts to individuals, but rather a dramatic drop in the discounts offered to HMOs. Although, it is most certainly economically inefficient to enact Allen-Kennedy, that should not end the debate. Many values aside from efficiency are of equal importance and are worthy of consideration.

The principle behind this section is that price controls on prescription drugs are not the only approach to bringing down high drug costs, because the market is working toward bringing prices down itself. Other items previously discussed throughout this paper could be noted here as well. Increasing generic and branded competition, for instance, are examples of the market working to cut drug costs without the government setting prices. There is no question that market forces do operate in many drug markets and that government's efforts to inhibit those very forces threaten to upset important progress in cutting prescription drug costs. Managed care has an important role in pushing drug prices down in an efficient manner. It is also clear that those mechanisms are less than perfect and that they may need to be supplemented with other strategies.

VII. CONCLUSION

The issue of prescription drug pricing has again returned to the political dialogue after a short respite. The 2000 elections may change the complexion of the Congress or the policy aspirations of the White House. It is impossible to guess whether the drive for controls is likely to recede after this point. As the number of uninsured Americans continues to rise, pressure will grow to cover these citizens. Coverage is likely to be provided only if overall health care spending is reduced. It is not hard to see how these forces will tend to bring pressure to bear on the pricing practices of pharmaceutical companies.

Proponents of price regulation are right to note that many of the industry's most ardent defenders on price issues oppose expanding health insurance coverage for prescription drugs. Sometimes industry defenders seem to fail to offer *any* meaningful set of policy solutions. Many scholars who defend the industry also fail to acknowledge that some drug prices are simply too high. The industry, on the other hand, is right to point out that the consumer advocates often underestimate the potentially deleterious impact that price regulation can have on research incentives. The industry's detractors also frequently look at drug prices in a vacuum, without regard to the costly therapies for which these drugs are often substitutes.

The use of managed care has evolved as a particularly promising tool to bring down drug costs. These market-based approaches should be used whenever possible. It is also clear that the heavy use of patents in the pharmaceutical arena means that the market for drugs is not exactly the same as the market for other goods and services, even if some measure of competition does prevail among different drugs. If government intervenes to grant a patent, there may be cases where government should intervene to prevent the patent holder from exploiting that benefit. In addition to patents, the government spends large sums on research that benefits drug companies, and they also allow them to take advantage of generous tax credits. Any argument that drug companies do all of the work themselves is misleading; government gives them a fair amount of help along the way. Whenever designing solutions, government nevertheless must take care to consider the massive R&D needs of drug companies, as well as the rather mixed record that Europeans have had in balancing the needs of consumers and pharmaceutical companies.

There is much at stake in this debate. The U.S. is the world leader in the development of breakthrough drugs, and future research in the fields of biotechnology and genomics make the coming century a potentially revolutionary one. At the same time, many of these drugs are likely to be priced out of reach for many Americans. The challenge for policy-makers is to find a way to increase coverage of prescription drugs through insurance plans, while preserving the profitability of the pharmaceutical industry. There is great

disagreement about the effects of price regulation in other nations and what such approaches might mean for the U.S. Finally, there may be solutions to this problem that avoid the chaos of laissez-faire, without using the blunt instrument that is stringent price regulation. The challenge for policy makers is to navigate that difficult divide.

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